REMARKS/ARUGMENTS

Upon entry of this amendment, claims 3 and 8 will be amended, whereby claims 1-8, 10-18 and 20-25 will remain pending. Claim 1 is the sole independent claim.

By the amendment herein, claim 3 has been amended to present the claim in better idiomatic form. Moreover, claim 8 has amended to clarify its language.

Reconsideration and allowance of the application are respectfully requested.

Response To 35 U.S.C. 112, First Paragraph, Enablement Rejection

Claims 1-8, 10-18 and 20-25 are rejected under 35 U.S.C. 112, first paragraph, because the rejection asserts that the claims fail to comply with the enablement requirement.

The rejection asserts that the invention provides a formulation for gastric drug delivery wherein the formulation adheres to the selected site in the intestines, that the formulations of the invention are patch or tape-like formulations, and that the art does not teach tape or patch-like formulations that are orally ingested and adhere to the intestines.

In response, Applicants respectfully submit that the rejection does not clearly state what the Examiner considers to be non-enabled. However, it appears that the Examiner is asserting there is no evidence that once orally administered the formulation according to the invention actually reaches its target of a selected site in the intestines. The Examiner contends that there is no showing that the formulation passes through the stomach after oral administration and actually adheres to the intestines as is required by the instant claims. The rejection asserts that the specification sets forth examples of formulation being placed in the duodenum of rats by surgical means but does not set forth

examples of the formulation being orally administered where the formulation would be subject to the entire digestive tract, including the mouth and stomach.

Applicant respectfully submits that examples in the specification provide examples of both oral administration as well as surgery being utilized to place formulations in the duodenum through a cut in the stomach near the pylorus and the location of the formulation being subsequently determined.

Applicant respectfully submits that Applicant's specification discloses Applicant's invention so that one having ordinary skill in the art can practice the invention without undue experimentation following the guidance provided in Applicant's specification. Thus, Applicant's specification describes that the adhesion-site controlling layer dissolves at a suitable site in the GI-tract and that it is made of pH dependent enteric polymer. One having ordinary skill in the art would readily understand that an enteric polymer does not dissolve in the stomach, but dissolves in the intestines. This is the definition of enteric.

For example, the Examiner's attention is directed to the definition of "enteric coated" printed on January 10, 2005 from the web site (copy of definition attached) http://altmedicine.about.com/library/bldef-enteric_coated.htm, which defines "enteric coated" as "A capsule or tablet with a protective coating that allows it to reach the intestines without being dissolved in the stomach."

Still further, the Examiner's attention is directed to the definitions of "enteric coating" and "enteric coated tablet" printed on January 10, 2005 from the web sites (copy of definitions attached) http://dictionarybarn.com/ENTERIC-COATED-TABLET.php and http://dictionarybarn.com/ENTERIC-COATING.php, which define "enteric coating" as "A

coating put on a capsule or pill so that it does not dissolve until it reaches the small intestine.", and "enteric coated tablet" as "An oral dosage form in which a tablet is coated with a material to prevent or minimise dissolution in the stomach but allow dissolution in the small intestine. This type of formulation either protects the stomach from a potentially irritating drug (e.g., aspirin) or protects the drug (e.g., erythromycin) from partial degradation in the acidic environment of the stomach." Thus, for example, "enteric-coated aspirin" is "aspirin that is treated to pass through the stomach unaltered and to dissolve in the intestines" such as defined in the print out on January 10, 2004 from the web site http://wordreference.com/definition/enteric-coated+aspirin.

Applicant notes that the adhesion site-controlling layer used in the present invention is composed of an enteric polymer as described in the specification. The adhesion site-controlling layer does not have a function of being attached to the mucous membrane. A drug-carrying layer for containing a drug and an adhesive is attached next to the adhesion site-controlling layer. This drug-carrying layer has a function of being attached to the mucous membrane.

It is also well known to those having ordinary skill in the pharmaceutical art that enteric polymers do not dissolve in water or acidic aqueous solutions. Accordingly, an adhesion site controlling layer in the present invention does not dissolve in water nor acidic aqueous solutions so that a drug-carrying layer for containing a drug and an adhesive does not come out in those media.

The pH condition in the stomach is acidic due to gastric juice. An adhesion site-controlling layer in the present invention does not dissolve in the stomach and a drug-carrying layer for containing a drug and an adhesive does not come out in the

stomach. Thus, the oral formulation of the present invention does not attach to the stomach.

Expanding upon the above, the Examiner's attention is directed, for example, to Applicant's specification at page 7, beginning at line 13, for a discussion of oral administration of the formulation of Applicant's invention with the adhesion site-controlling layer dissolving at an unique site in the digestive tract. Moreover, the subsequent paragraph appearing on page 8 of Applicant's specification provides examples of adhesion site-controlling layer substances including pH dependent enteric polymer.

Applicant respectfully submits that sufficient guidance has been presented in the application so that one having ordinary skill in the art can practice Applicant's invention without undue experimentation. In particular, Applicant's have provided a thorough disclosure of formulations according to Applicant's invention, and one having ordinary skill in the art can practice Applicant's disclosed and claimed invention without undue experimentation.

Applicant respectfully submits that the burden of showing lack of enablement is on the Patent and Trademark Office. Under the present circumstances, Applicant's claims are enabling, whereby the rejection of record should be withdrawn.

Response To Rejection Under 35 U.S.C. 112, Second Paragraph

Claims 1-8, 10-18 and 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

With respect to claim 1, the rejection questions the language pertaining to the site-controlling layer for attaching the formulation to a selected site in the intestines, and that the drug-carrying layer contains an adhesive to attach the drug-containing layer to the selected site in the intestines.

In response, Applicant refers the Examiner to the specification, such as at page 8, second full paragraph, wherein it is disclosed that the adhesive is used for attaching the drug-carrying layer to the mucosal membrane of the digestive tract when the adhesion site-controlling layer dissolves at a site selected in the digestive tract. Thus, the adhesion site-controlling layer and drug-carrying layer are structured and arranged so that the adhesion site-controlling layer initially attaches to the site and then, when the adhesion site-controlling layer dissolves, the drug-carrying layer attaches to the mucosal membrane of the digestive tract. Accordingly, claim 1 definitely recites Applicant's invention.

Regarding claim 8, the claim has been amended herein in accordance with page 11, beginning at line 6 of the specification, to even more clearly recite that the protecting layer is a film or a capsule, each of said film or capsule being composed of at least one of a water-insoluble polymer and a wax.

Accordingly, the indefiniteness rejection under 35 U.S.C. 112, second paragraph, should be withdrawn. Moreover, if the Examiner deems that amendments would be

beneficial to Applicant's claimed invention, the Examiner is respectfully requested to contact the undersigned by telephone to discuss the same.

CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejection of record, and allow each of the pending claims.

Applicant therefore respectfully requests that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
Kanji TAKADA

Bruce H. Bernstein
Reg. No. 29,027

January 10, 2005
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191

Arnold Turk
Reg. No. 33,094

Alternative Medicine

Enteric-coated

<Back to Last Page> <Full Glossary>

Definition: A capsule or tablet with a protective coating that allows it to reach the intestines without being dissolved in the stomach.

Pronunciation: [en'taeric] • (noun)

<Back to Last Page> <Full Glossary>

Dictionary definition of ENTERIC COATED TABLET

DictionaryBarn
A medical dictionary

Browse Dictionary by alphabet

0 1 2 3 4 5 6 7 8 9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Top Words

en bloc
en grappe
en thyrse
en-
enacyloxin oxidase
enaemiasis
enalapril
enalapril maleate
enalaprilat
enaliosaur
enaliosauria
enaliosaurian
enamel
enamel cap
enamel cell
enamel cleavage
enamel cleaver
enamel cuticle
enamel drop
enamel dysplasia
enamel epithelium
enamel fibres
enamel fissure
enamel germ
enamel hypocalcification
enamel hypoplasia
enamel lamella
enamel layer
enamel ledge
enamel membrane
enamel microabrasion
enamel niche
enamel nodule
enamel organ
enamel pearl
enamel prisms
enamel projection
enamel pulp
enamel rod
inclination

An oral dosage form in which a tablet is coated with a material to prevent or minimise dissolution in the stomach but allow dissolution in the small intestine. This type of formulation either protects the stomach from a potentially irritating drug (e.g., aspirin) or protects the drug (e.g., erythromycin) from partial degradation in the acidic environment of the stomach.

Please select first two letters of word you are looking for

E0 E1 E2 E3 E4 E5 E6 E7 E8 E9 EA EB EC ED EE EF EG EH EI EJ EK EL EM EN EO EP EQ ER ES ET EU EV EW EX EY EZ

Search the Web

Go

Powered by MyWay

Top Words

encephalocele
encephaloclastic microcephaly
encephalocraniocutaneous lipomatosis
encephalocystocele
encephaloduroarteriosynangios
encephalodynia
encephalodysplasia
encephalogram
encephalography
encephaloid
encephaloid cancer
encephalolith
encephalology
encephaloma
encephalomalacia
encephalomeningitis
encephalomeningocele
encephalomeningopathy
encephalomere
encephalometer
encephalomyelitis associated with carcinoma
encephalomyelitis virus, avian
encephalomyelitis virus, murine
encephalomyelitis, acute disseminated
encephalomyelitis, allergic
encephalomyelitis, enzootic porcine
encephalomyelitis, equine
encephalomyelitis, venezuelan equine
encephalomyelocele
encephalomyeloneuropathy
encephalomyelonic axis
encephalomyelopathy
encephalomyeloradiculitis
encephalomyeloradiculopathy

Dictionary definition of ENTERIC COATING

DictionaryBarn
A medical dictionary

Browse Dictionary by alphabet

0 1 2 3 4 5 6 7 8 9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Top Words

en bloc
en grappe
en thyrse
en-
enacyloxin oxidase
enaemiasis
enalapril
enalapril maleate
enalaprilat
enaliosaur
enaliosauria
enaliosaurian
enamel
enamel cap
enamel cell
enamel cleavage
enamel cleaver
enamel cuticle
enamel drop
enamel dysplasia
enamel epithelium
enamel fibres
enamel fissure
enamel germ
enamel hypocalcification
enamel hypoplasia
enamel lamella
enamel layer
enamel ledge
enamel membrane
enamel microabrasion
enamel niche
enamel nodule
enamel organ
enamel pearl
enamel prisms
enamel projection
enamel pulp
enamel rod
inclination

A coating put on a capsule or pill so that it does not dissolve until itreaches the small intestine.

Please select first two letters of word you are looking for

E0 E1 E2 E3 E4 E5 E6 E7 E8 E9 EA EB EC ED EE EF EG EH EI EJ EK EL EM EN EO EP EQ ER ES ET EU EV EW EX EY EZ

Search the Web

Go

Powered by MyWay

Top Words

encephalocele
encephaloclastic microcephaly
encephalocraniocutaneous lipomatosis
encephalocystocele
encephaloduroarteriosynangios
encephalodynia
encephalodysplasia
encephalogram
encephalography
encephaloid
encephaloid cancer
encephalolith
encephalology
encephaloma
encephalomalacia
encephalomeningitis
encephalomeningocele
encephalomeningopathy
encephalomere
encephalometer
encephalomyelitis associated with carcinoma
encephalomyelitis virus, avian
encephalomyelitis virus, murine
encephalomyelitis, acute disseminated
encephalomyelitis, allergic
encephalomyelitis, enzootic porcine
encephalomyelitis, equine
encephalomyelitis, venezuelan equine
encephalomyelocele
encephalomyeloneuropathy
encephalomyelonic axis
encephalomyelopathy
encephalomyeloradiculitis
encephalomyeloradiculopathy

English Definition

GO

Home
Suggestions

See Also:
Entebbe
Entelea
entellus
entente
entente cordiale
enter
enter upon
enteral
enteric
enteric-coated aspirin
enteric bacteria
enteric fever
enterics
entering
enteritis
enterobacteria
Enterobacteriaceae
enterobiasis
Enterobius

enteric-coated_aspirin:
in French
in Italian
in Spanish

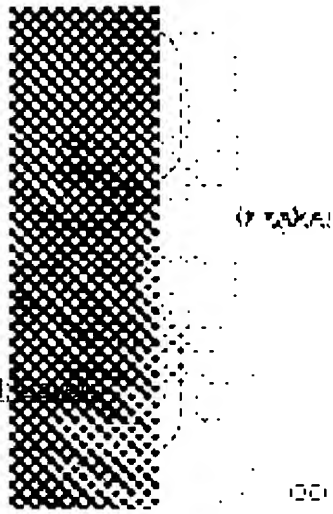
(symbols)

enteric-coated_aspirin

A *noun*

1 **enteric-coated_aspirin**
aspirin that is treated to pass through the stomach unaltered and to dissolve in the intestines

Category Tree:
entity
└substance; matter
└compound; chemical_compound
└salt
└salicylate
└aspirin; acetylsalicylic_acid
Empirin
└**enteric-coated_aspirin**



Need more information?
Ask a question in the new forum.

Look up "enteric-coated_aspirin" at Merriam-Webster
Look up "enteric-coated_aspirin" at dictionary.com